IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appeal No. (not yet assigned)	: Confirmation No. 1115
In re Application of	: Group Art Unit 3773
John O'Dea	: Examiner: Erezo, Darwin P.
Entitled:	: Docket No.: 011566US1
APPARATUS AND METHOD FOR RELIEVING DYSPNOEA	: Application Serial No. 10/796,585
	: Filed: March 9, 2004

APPELLANTS' BRIEF ON APPEAL

April 2, 2009

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is an Appeal from the decision of the Examiner dated September 22, 2008, rejecting Claims 17-26 and 30 of the above-captioned application. The claims involved in the appeal are set forth in Appendix 1, which is attached hereto.

Real Party In Interest

The real party in interest for the above-identified patent application is Caradyne Limited. This interest arises via an assignment from the inventor to Caradyne Limited. Caradyne Limited is a wholly owned subsidiary of Western Biomedical Technologies which is a wholly owned subsidiary of Respironics, Inc. Respironics, Inc. is a subsidiary of Philips Holding USA, Inc., which is a subsidiary of Koninklijke Philips Electronics N.V. **[Todd and Patti: Please confirm whether this is correct. The published application lists Caradyne as the assignee, and I did some research online to determine the connection to Respironics.]**

Related Appeals and Interferences

There are no prior and pending appeals, interferences or judicial proceedings known to Appellant or the Appellant's legal representative, which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

Status of Claims

Claims 17-26 and 30 stand rejected.

Claims 1-16 have been canceled and claims 27-29 have been withdrawn from further consideration.

Claims 17-26 and 30 are being appealed.

Status of Amendments

There have been no amendments filed subsequent to final rejection. The claims as they stand on Appeal are contained in the Appendix 1 to this Brief. A Response to Final Office Action was filed on December 11, 2008, and an Advisory Action was mailed on December 30, 2008.

Summary of Claimed Subject Matter

Independent claim 17

The present invention provides, in one embodiment, an apparatus 1 for providing pressure support to a subject. The apparatus 1 includes a housing 3 which defines a hollow interior region 4. A variable speed air blower motor 5 having an impeller 6 is located within the hollow interior region 4 for delivering an air supply to the subject at a pressure greater than ambient pressure. An air inlet port 7 in the housing 3 accommodates air into the hollow interior region 4 to be blown by the air blower motor 5 and the impeller 6 through an outlet port 8 for delivery to the subject. A communicating conduit 9 communicates the outlet port 8 with a mouthpiece 10 to which the air supply is delivered to the subject. A DC power source provided by a battery 20 is located in the housing 3 for powering the air blower motor 5. The speed of the blower motor 5 is controlled by a control circuit 22 for varying the flow rate of the air supply to the subject, for in turn varying the pressure at which the air supply is

delivered to the subject. In this embodiment, a pressure transducer 25 is located in the mouth piece 10 for monitoring air pressure in the mouth piece 10 during a plurality of complete breathing cycles so that the average intrinsic positive end-expiratory pressure of the subject may be determined. See, for example, page 9, line 12 through page 10, line 16 and Figures 1-3.

Signals from the pressure transducer 25 are relayed through hard wiring 27 to the control circuit 22. A microprocessor 28 in the control circuit 22 determines the average intrinsic positive end-expiratory pressure of the subject from the signals received from the pressure transducer 25 using one or more appropriate algorithms. For example, signals from five consecutive breathing cycles may be read by the microprocessor 28, and the average intrinsic positive end-expiratory pressure of the subject is determined over the five breathing cycles. The microprocessor 28 in the control circuit 22 controls the control circuit 22 for in turn controlling the air blower motor 5 for delivering the air supply at an appropriate flow rate to the mouthpiece 10 so that the air supply delivered to the mouthpiece 10 is at a pressure matched to the determined average intrinsic positive end-expiratory pressure. The control circuit 22 controls the air blower motor 5 for maintaining the pressure of the air supply at the appropriate pressure until signals received from the pressure transducer 25 in the mouthpiece 10 indicate that a further change in the average intrinsic positive end-expiratory pressure has occurred, at which time the control circuit 22 again controls the blower motor 5 to again match the pressure of the air supply to the newly determined average intrinsic positive end-expiratory pressure. See, for example, page 11, line 24 through page 12, line 13.

The present invention also provides, in another embodiment, an apparatus 40 for providing pressure support to a subject that is similar to the apparatus 1. The main difference between the apparatus 40 and the apparatus 1 is that the blower motor 5 in apparatus 40 is a constant speed motor, and thus, delivers the air supply at a constant pressure. In this embodiment, the air supply is provided to the subject through a mouth and nasal mask 41 within which the pressure transducer 25 is located. An exhaust port 42 from the mouth and nasal mask 41 exhausts expired air from the subject. A variable pressure regulating valve 44 is located in the exhaust port 42 for controlling the pressure of the air supply in the mouth and nasal mask 41. The valve

44 is hard wired to the control circuit 22, and the control circuit 22 controls the valve 44 for maintaining the pressure in the mouth and nasal mask 41 at a pressure similar to the average intrinsic positive end-expiratory pressure determined by the microprocessor 28 in response to signals received from the pressure transducer 25.

Operation of the apparatus 40 is substantially similar to that of the apparatus 1. The average intrinsic positive end-expiratory pressure of the subject is determined by the microprocessor 28 of the control circuit 22 from signals read from the pressure transducer 25. On determining the average intrinsic positive end-expiratory pressure, the control circuit 22 then sets the valve 44 appropriately so that the air supply in the mouth and nasal mask 41 is at a pressure similar to the average intrinsic positive end-expiratory pressure determined by the microprocessor 28. On the microprocessor 28 determining a change in the average intrinsic positive end-expiratory pressure, the control circuit 22 resets the valve 44 appropriately, so that the air supply in the mask 41 is again at a pressure similar to the new average intrinsic positive end-expiratory pressure. See, for example, page 13, line 19 through page 14, line 19 and Figures 5-6.

Independent claim 30

The present invention also provides a method for relieving dyspnoea in a subject. The blower motor 5 (of either the apparatus 1 or the apparatus 40) delivers an air supply to the subject at a pressure greater than ambient pressure through the blower motor 5 having an impeller 6 is located within the hollow interior region 4 for delivering an air supply to the subject at a pressure greater than ambient pressure. Signals from the pressure transducer 25 (of either the apparatus 1 or the apparatus 40) are relayed through hard wiring 27 to the control circuit 22. The microprocessor 28 in the control circuit 22 determines the average intrinsic positive end-expiratory pressure of the subject from the signals received from the pressure transducer 25 using one or more appropriate algorithms. For example, signals from five consecutive breathing cycles may be read by the microprocessor 28, and the average intrinsic positive end-expiratory pressure of the subject is determined over the five breathing cycles. In one embodiment, the microprocessor 28 in the control circuit 22 controls the control circuit 22 for in turn controlling the air blower motor 5 for delivering the air supply at an appropriate flow rate to the mouthpiece 10 so that the air supply delivered to the

mouthpiece 10 is at a pressure matched to the determined average intrinsic positive end-expiratory pressure. See, for example, page 11, line 24 through page 12, line 13. In another embodiment, on determining the average intrinsic positive end-expiratory pressure, the control circuit 22 then sets the valve 44 located in the exhaust port 42 appropriately so that the air supply in the mouth and nasal mask 41 is at a pressure similar to the average intrinsic positive end-expiratory pressure determined by the microprocessor 28. See, for example, page 13, line 19 through page 14, line 19 and Figures 5-6.

Means Plus Function Elements

Claim 17 recites "monitoring means for monitoring a characteristic associated with a breathing cycle of the subject." A pressure transducer 25 is located in the mouth piece 10 or the mask 41 for monitoring air pressure in the mouth piece 10 or the mask 41 during a plurality of complete breathing cycles so that the average intrinsic positive end-expiratory pressure of the subject may be determined. See, for example, page 10, lines 13-16 and Figures 1-3 and page 13, lines 25-27.

Claim 17 also recites "controlling means for determining an average intrinsic positive end-expiratory pressure over a plurality of breathing cycles based on an output of the monitoring means, and for controlling the gas flow generating system such that a pressure of the flow of gas delivered to the subject during at least a portion of an expiratory phase of a breathing cycle substantially corresponds to the average intrinsic positive end-expiratory pressure." In one embodiment, a microprocessor 28 in the control circuit 22 determines the average intrinsic positive end-expiratory pressure of the subject from the signals received from the pressure transducer 25 using one or more appropriate algorithms. The microprocessor 28 in the control circuit 22 controls the control circuit 22 for in turn controlling the air blower motor 5 for delivering the air supply at an appropriate flow rate to the mouthpiece 10 so that the air supply delivered to the mouthpiece 10 is at a pressure matched to the determined average intrinsic positive end-expiratory pressure. See, for example, page 11, line 24 through page 12, line 13. In another embodiment, The average intrinsic positive end-expiratory pressure of the subject is determined by the microprocessor 28 of the control circuit 22 from signals read from the pressure transducer 25. On

determining the average intrinsic positive end-expiratory pressure, the control circuit 22 then sets the valve 44 appropriately so that the air supply in the mouth and nasal mask 41 is at a pressure similar to the average intrinsic positive end-expiratory pressure determined by the microprocessor 28. See, for example, page 13, line 19 through page 14, line 19 and Figures 5-6.

Grounds of Rejection to be Reviewed on Appeal

Claims 17, 18, 20-22, 24 25 and 30 stand rejected under 35 U.S.C. § 103 as being unpatentable over United States Patent No. 5,660,170 to Rajan et al. in view of United States Patent No. 4,444,201 to Itoh.

Claims 19 and 26 stand rejected under 35 U.S.C. § 103 as being unpatentable over Rajan in view of Itoh and further in view of United States Patent No. 5,551,419 to Froechlich et al.

Claim 23 stands rejected under 35 U.S.C. § 103 as being unpatentable over Rajan in view of Itoh and further in view of United States Patent No. 5,868,133 to Devries et al.

Argument

Rejections under 35 U.S.C. § 103(a)

Claims 17-26 and 30

Claim 17 recites an apparatus for providing pressure support to a subject that includes "controlling means for determining an average intrinsic positive end-expiratory pressure over a plurality of breathing cycles based on an output of the monitoring means, and for controlling the gas flow generating system such that a pressure of the flow of gas delivered to the subject during at least a portion of an expiratory phase of a breathing cycle substantially corresponds to the average intrinsic positive end-expiratory pressure." Similarly, claim 30 recites a method for relieving dyspnoea in a subject that includes "determining an intrinsic positive end-expiratory pressure of the subject over a plurality of breathing cycles" and "controlling the pressure of the flow of gas delivered to the subject during an expiratory phase of a breathing cycle such that the pressure of the flow of gas substantially corresponds to an average intrinsic positive end-expiratory pressure."

Rajan relates to determining an optimal "opening pressure" for a patient, which is a pressure at which the alveoli begin to open. The purpose for and significance of that determination is so that the lung system in Rajan can provide the determined opening pressure to the patient during exhalation to ensure that the patient receives a pressure sufficient to open the alveoli. The opening of the alveoli in this manner allows for the efficient and proper gas exchange during the provision of therapy. Rajan describes a relatively elaborate technique for determining the opening pressure. That technique is not, however, based on a calculated average positive end-expiratory pressure (PEEP). It is thus clear that Rajan discloses neither "determining an average intrinsic positive end-expiratory pressure over a plurality of breathing cycles based on an output of the monitoring means" nor "controlling the gas flow generating system such that a pressure of the flow of gas delivered to the subject during at least a portion of an expiratory phase of a breathing cycle substantially corresponds to the average intrinsic positive end-expiratory pressure" as recited in claim 17. It is also clear that Rajan discloses neither "determining an intrinsic positive end-expiratory pressure of the subject over a plurality of breathing cycles" nor "controlling the pressure of the flow of gas delivered to the subject during an expiratory phase of a breathing cycle such that the pressure of the flow of gas substantially corresponds to an average intrinsic positive end-expiratory pressure" as recited in claim 30. As noted above, in Rajan, the optimal opening pressure (not based on average PEEP) is determined and that optimal opening pressure is provided to the patient during the expiratory phase in order to open the alveoli. The Examiner has acknowledged that Rajan "is silent with regards to averaging the PEEP." The Examiner states, however, that Itoh discloses determining average PEEP and that it therefore would have been obvious to modify Rajan to determine an average PEEP (and presumably also then provide a pressure that substantially corresponds to the average PEEP to the patient during the *expiratory phase* as required in the claims). The Applicant strongly disagrees.

Itoh describes a respiration monitoring apparatus that includes a signal processing circuit which detects the end of the respective expiratory periods based on output signals from included meters (which denote the flow rate of breathed air flow) and stores the average value of the airway pressures determined at the end of the

respective expiratory periods. In addition, when the measured airway pressure falls below the stored average value, the apparatus issues a detection signal denoting this condition and changes a display pattern on the monitor of the apparatus. Itoh does not disclose providing a pressure that substantially corresponds to the average PEEP to the patient, as the average PEEP level is used only for detecting an alarm condition for notifying the patient.

It is well settled that if a modification proposed by an examiner would render the prior art device being modified unsatisfactory for its intended purpose, then the proposed modification is not proper. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)[1]; MPEP §2143.01 V. Furthermore, as stated recently by the Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, 127 S.Ct. 1727 (2007), in determining whether a proposed claim would have been obvious under 35 U.S.C. § 103 "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." Here, there is clearly no reason that would have prompted a person of ordinary skill in the relevant field to modify the system of Rajan to determine an average PEEP *(as opposed to an optimal opening pressure)* and then provide a pressure that substantially corresponds to the average PEEP *(as opposed to an optimal opening pressure)* to the patient *during the expiratory phase* as required in the claims. The *whole purpose and entire focus* of Rajan is to determine the optimal opening pressure of the patient so that the lung system in Rajan can then provide the determined optimal opening pressure to the patient during exhalation to ensure that the patient receives a pressure sufficient to open the alveoli. Thus, the modification proposed by the Examiner would clearly make Rajan unfit and inoperable for its

[1] In *In re Gordon*, the claimed device was a blood filter assembly for use during medical procedures wherein both the inlet and outlet for the blood were located at the bottom end of the filter assembly, and wherein a gas vent was present at the top of the filter assembly. The prior art reference taught a liquid strainer for removing dirt and water from gasoline and other light oils wherein the inlet and outlet were at the top of the device, and wherein a pet-cock (stopcock) was located at the bottom of the device for periodically removing the collected dirt and water. The reference further taught that the separation is assisted by gravity. The Board concluded the claims were *prima facie* obvious, reasoning that it would have been obvious to turn the reference device upside down. The Federal Circuit reversed, finding that if the prior art device was turned upside down it would be *inoperable for its intended purpose* because the gasoline to be filtered would be trapped at the top, the water and heavier oils sought to be separated would flow out of the outlet instead of the purified gasoline, and the screen would become clogged.

intended purpose (which is to determine and provide an optimal opening pressure to the patient) as the optimal opening pressure (determined in the manner described in Rajan) would no longer be determined and provided to the patient. In instead, with the Examiner' proposed modification, a pressure equal to average PEEP would always be provided to the patient. Furthermore, Itoh merely describes the determination of an average PEEP solely for purposes of alarm detection.

Moreover, in the final Office Action dated September 28, 2008 and in the Advisory Action dated December 30, 2008, the Examiner cited to col. 8, lines 27-32 of Rajan. That portion of Rajan states:

> The regulating unit 2 is adapted to deliver inspiration pulses of any shape regarding pressure. In other words, the regulating unit 2 can deliver inspiration pulses with a controlled pressure, which varies in a predetermined manner. For example, the regulating unit 2 can deliver inspiration pulses 18, 20 and 22 as shown in FIG. 2. Inspiration pulse 18 has a start pressure at PEEP level and an end pressure at PIP level.

As is clear from the above, the portion of Rajan that the Examiner is relying on for a disclosure of PEEP (positive end expiratory pressure) relates to the pressure provided during *the inspiratory phase of the patient's breathing cycle (i.e., " the inspiration pulse")*. The optimal opening pressure is then determined during the delivery of that inspiration pulse. See, for example, col. 2, lines 33-44. Claim 17 recites "controlling the gas flow generating system such that a pressure of the flow of gas delivered to the subject *during at least a portion of an expiratory phase of a breathing cycle* substantially corresponds to the average intrinsic positive end-expiratory pressure." Similarly, claim 30 recites "controlling the pressure of the flow of gas delivered to the subject *during an expiratory phase of a breathing cycle* such that the pressure of the flow of gas substantially corresponds to an average intrinsic positive end-expiratory pressure." Thus, the Examiner's reliance on a description of PEEP in Rajan is misplaced.

Thus, for the reasons stated above, the Applicant submits that claims 17 and 30 would not have been obvious over Rajan in view of Itoh and therefore requests that the rejection under 35 U.S.C. § 103 be withdrawn. In addition, because claims 18-26 depend, directly or indirectly, from claim 17, they are likewise believed to be allowable.

Summary and Conclusion

Claims 17-26 and 30 are patentable over the cited references.

Therefore, it is requested that the Board reverse the Examiner's rejections of claims 17-26 and 30 and remand the application to the Examiner for the issuance of a Notice of Allowance for claims 17-26 and 30.

Respectfully submitted,

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APPENDIX 1 (Claims Appendix)

1-16. (Cancelled).

17. An apparatus for providing pressure support to a subject, the apparatus comprising:

a gas flow generating system adapted to provide a flow of gas;

monitoring means for monitoring a characteristic associated with a breathing cycle of the subject;

controlling means for determining an average intrinsic positive end-expiratory pressure over a plurality of breathing cycles based on an output of the monitoring means, and for controlling the gas flow generating system such that a pressure of the flow of gas delivered to the subject during at least a portion of an expiratory phase of a breathing cycle substantially corresponds to the average intrinsic positive end-expiratory pressure.

18. The apparatus as claimed in claim 17, wherein the controlling means controls the gas flow generating system such that the pressure of the flow of gas delivered to the subject during at least a portion of an inspiratory phase of a breathing cycle is at a pressure greater than the average intrinsic positive end-expiratory pressure.

19. The apparatus as claimed in claim 17, wherein the gas flow generating system includes a blower motor, and wherein the controlling means controls the pressure provided by that gas flow generating system by controlling an operating speed of the blower motor.

20. The apparatus as claimed in claim 17, wherein the monitoring means is located proximate to an airway of the subject.

21. The apparatus as claimed in claim 20, further comprising:

a patient circuit having a first end operatively connected to the gas flow generating system and a second end; and

a patient interface operatively connected to the second end of the patient circuit, and wherein the monitoring means is operatively connected to the patient interface.

22. The apparatus as claimed in claim 17, wherein the monitoring means is connected to the controlling means by a wire.

23. The apparatus as claimed in claim 17, wherein the monitoring means includes means for transmitting a wireless signal to the controlling means, and wherein the controlling means includes receiving means for receiving the wireless signal.

24. The apparatus as claimed in claim 17, wherein the monitoring means is a pressure transducer.

25. The apparatus as claimed in claim 17, wherein the apparatus is portable and is adapted for use by an ambulatory subject.

26. The apparatus as claimed in claim 17, wherein the gas flow generating system comprises an electrically powered blower motor.

27-29. (Withdrawn)

30. (Previously Presented) A method for relieving dyspnoea in a subject, the method comprising the steps of:

delivering a flow of gas to an airway of a subject at a pressure greater than ambient;

determining an intrinsic positive end-expiratory pressure of the subject over a plurality of breathing cycles; and

controlling the pressure of the flow of gas delivered to the subject during an expiratory phase of a breathing cycle such that the pressure of the flow of gas substantially corresponds to an average intrinsic positive end-expiratory pressure.

APPENDIX 2 (Evidence Appendix)

None.

APPENDIX 3 (Related Proceedings Appendix)

None.